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December 14, 2022

*Life Sciences
Claims 2022: Redefining Normalcy*

Presenters

- ▶ Jennifer Heis, Esquire
- ▶ Lauren Hulbert, CPCU, AIC, AIS
- ▶ Andy Hall, Esquire



Jennifer Heis, Esquire

▶ Jennifer Heis is a partner in the Cincinnati office of Ulmer Berne. Jennifer has more than 20 years of experience defending manufacturers and distributors of pharmaceutical products and dietary supplements. She has represented her clients in complex litigation, including multidistrict litigation and consolidated state court proceedings, as well as individual cases throughout the country.



Lauren Hulbert, CPCU, AIC, AIS

- ▶ Lauren joined Medmarc in August 2005. Lauren is responsible for investigating coverage and liability, managing reserves and litigation, monitoring outside service providers, negotiating settlements, and maintaining good client relations. Due to her varied experience, she has handled claims of increasing complexity and severity in her time at Medmarc.



Andrew Hall, Esquire

- ▶ Andy joined Medmarc in 2017 as a Senior Claims Examiner. He is responsible for claims investigation, coverage analysis, managing reserves, negotiating settlements, monitoring defense counsel activities, and maintaining good client relations. Andy also works on the product development team where he assists with drafting language for our new products.



Agenda

- Welcome
- Industry trends
- Emerging technologies
- Key Developments of 2022
- Excessive Verdicts & Factors
- Looking Forward to 2023
- FDA Regulatory update





Talent Shortages

Audience Participation Question #1!

- ▶ In 2022, has it taken your company or your clients longer to fill open positions:
 - ▶ Yes
 - ▶ No

- ▶ Talent shortages for life science companies predate the COVID-19 pandemic
- ▶ Deficits exist across educational spectrums and locations
- ▶ Life science job demand outpaces the U.S. job market
- ▶ The data on the next slide is from the Biotechnology Education Foundation on focuses for the 2010-2020 in Massachusetts:

See: Sunny Schwartz, A worker shortage for life sciences, Boston Globe, January 6, 2020, accessed at <https://www.bostonglobe.com.cdn.ampproject.org/c/s/www.bostonglobe.com/2020/01/06/opinion/worker-shortage-life-sciences/?outputType=amp> (last visited 11/22/2022).

Talent Shortages Pre-Pandemic

PhD

**Demand:
140%
increase**

**Degree
Conferrals:
Same**

BS

**Demand:
120%
increase**

**Labor
Market: 37%
increase**

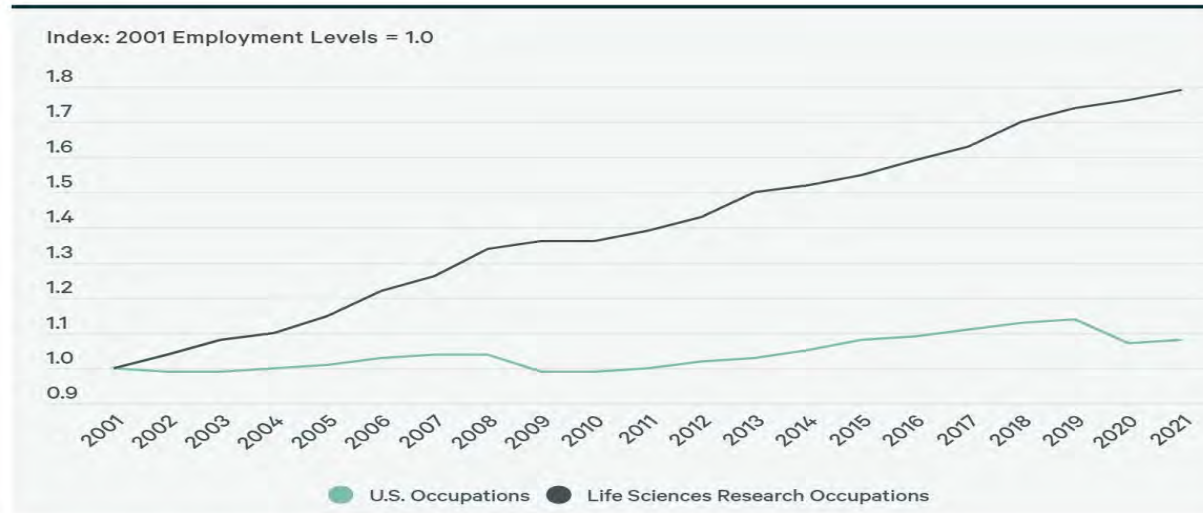
**Assoc./
HS**

**Demand:
120%
increase**

**Labor
Market:
Same**

Talent Shortages Pre-Pandemic, cont'd

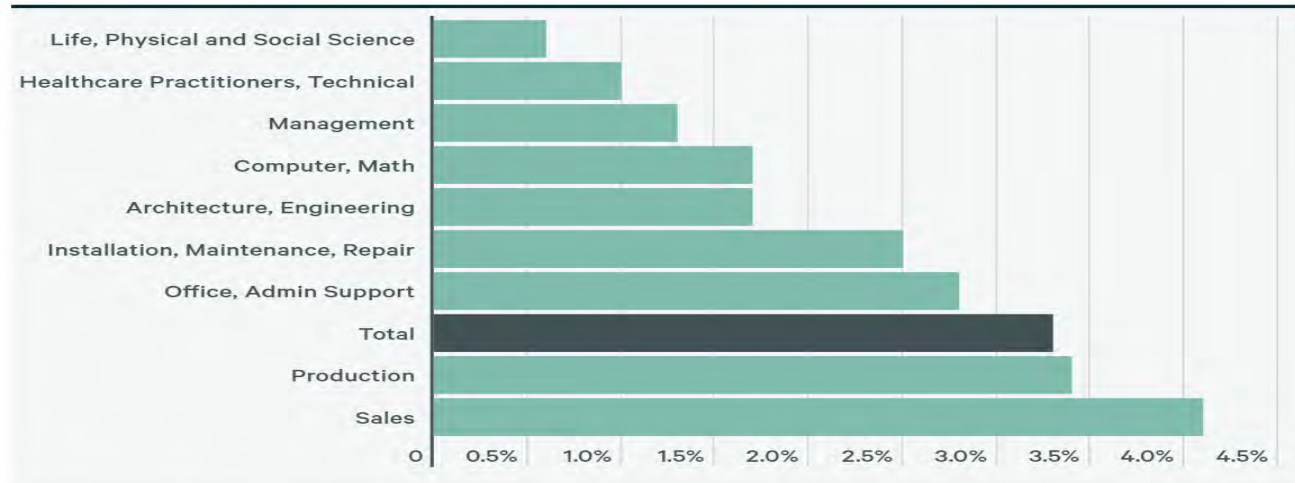
Changes since 2001 in U.S. Life Science Research Occupations v. All U.S. Occupations



Source: U.S. Bureau of Labor Statistics, CBRE Research, Q1 2022.

See: *Life Sciences Research Talent 2022*, June 13, 2022, <https://www.cbre.com/insights/reports/us-life-sciences-talent-2022> (last visited 11/22/2022).

Unemployment Rates by U.S. Occupational Category



Source: U.S. Bureau of Labor Statistics, April 2022. Not Seasonally Adjusted Data.

See: *Life Sciences Research Talent 2022*, June 13, 2022, <https://www.cbre.com/insights/reports/us-life-sciences-talent-2022> (last visited 11/22/2022).

Talent Shortages Post-Pandemic, cont'd



- ▶ In 2020, U.S. life science employment base increased 1.4% (All other industries had 5.1% loss)
- ▶ It takes 105 days on average to fill non-executive position in life science sector.
- ▶ Difficulty filling jobs is \$500 a day loss per job

See: 4 talent trends for life sciences organizations to drive growth in a world of disruption, Randstad Sourceri, July 7, 2022, accessed at <https://insights.randstadsourceright.com> (last visited 11/22/2022).

Talent Shortages—Potential Claims/Litigation



- ▶ Vacancies in positions critical to design/manufacturing process
 - ▶ EXAMPLE: Your company has an employee that inspects component parts upon delivery. She leaves and bad batch of component parts used in your product.
- ▶ Employees taking on additional responsibilities
 - ▶ EXAMPLE: Using the same example as above, one of your company's engineers takes on the job of inspecting component parts, but does not identify the component part's non-conformity before it is used on your company's product.

Talent Shortages—Potential Claims/Litigation, cont'd



- ▶ Underqualified or inexperienced people filling vacancies
 - ▶ EXAMPLE: You have new employee who is responsible for making sure that your company's birth control pills are packaged correctly. That employee mixes up the pills and they are packaged in the wrong order.



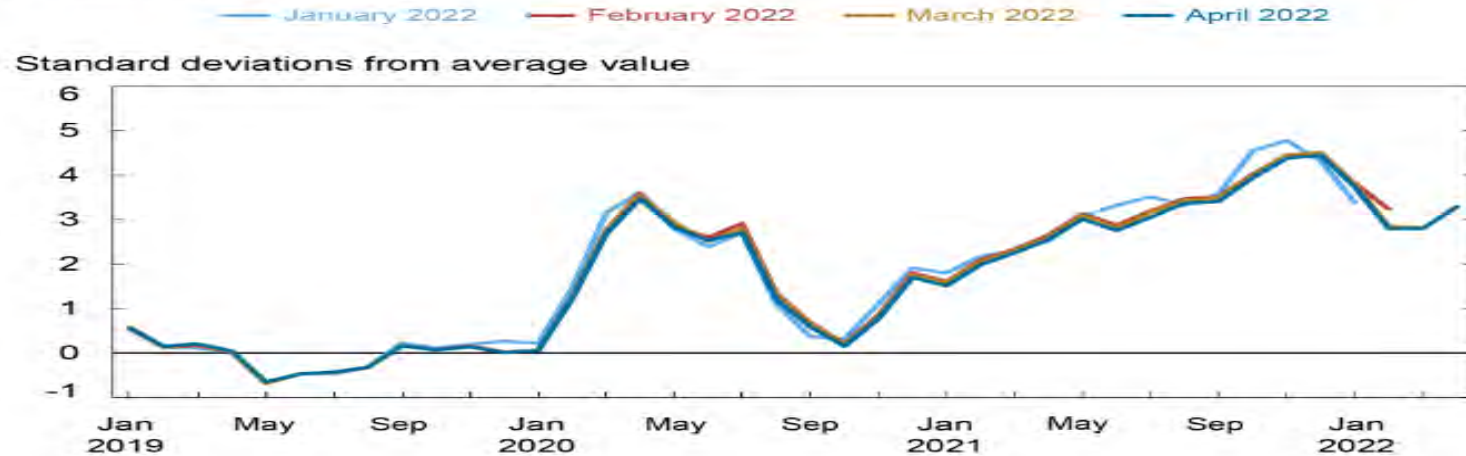
Supply Chain Issues

Audience Participation Question #2!

- ▶ Have you or your insureds experienced any of the below in 2022 (select all that apply):
- ▶ (A) Delays from suppliers;
 - ▶ (B) Increased prices for component parts;
 - ▶ (C) Inconsistent demand for your products;
 - ▶ (D) Labor and talent shortages.

Supply Chain Issues—Across all Industries

Revised and Realized Data Can Alter Previous Supply Chain Pressure Readings



Sources: Bureau of Labor Statistics; Harper Petersen Holding GmbH; Baltic Exchange; THS Markit; Institute for Supply Management; Haver Analytics; Bloomberg L.P.; authors' calculations.

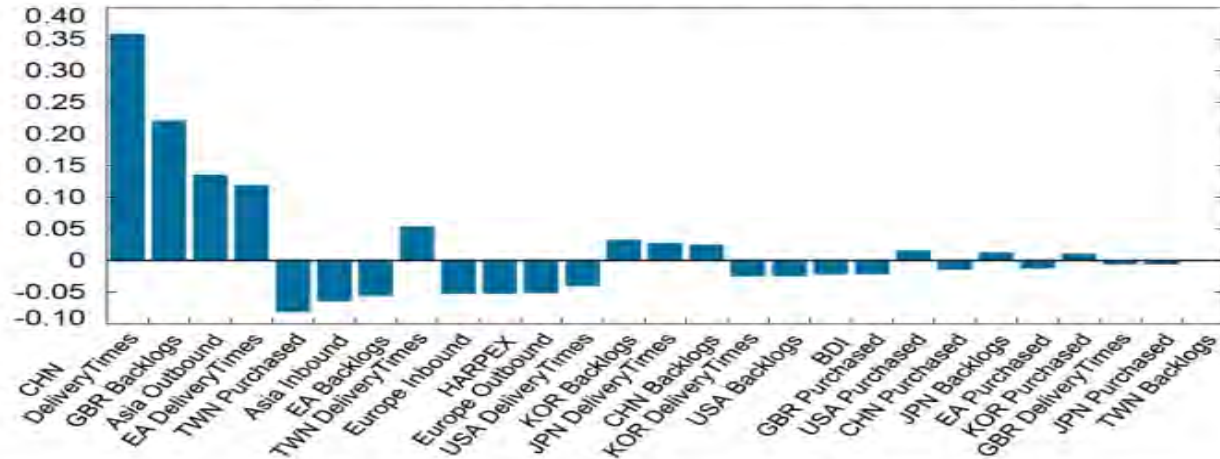
Note: Index is scaled by its standard deviation.

Global Supply Chain Pressure Index: May 2022 Update, Gialucxa Benigno, Julian di Giovanni, Jan J.J. Groen, and Adam Noble, May 18, 2022, accessed at <https://libertystreeteconomics.newyorkfed.org/2022/05/global-supply-chain-pressure-index-may-2022-update/> (last visited 12/5/2022).

Supply Chain Issues—Across all Industries

Global Supply Chain Pressures Worsen in April 2022

Contribution to change in GSCPI (in standard deviations), March-April 2022



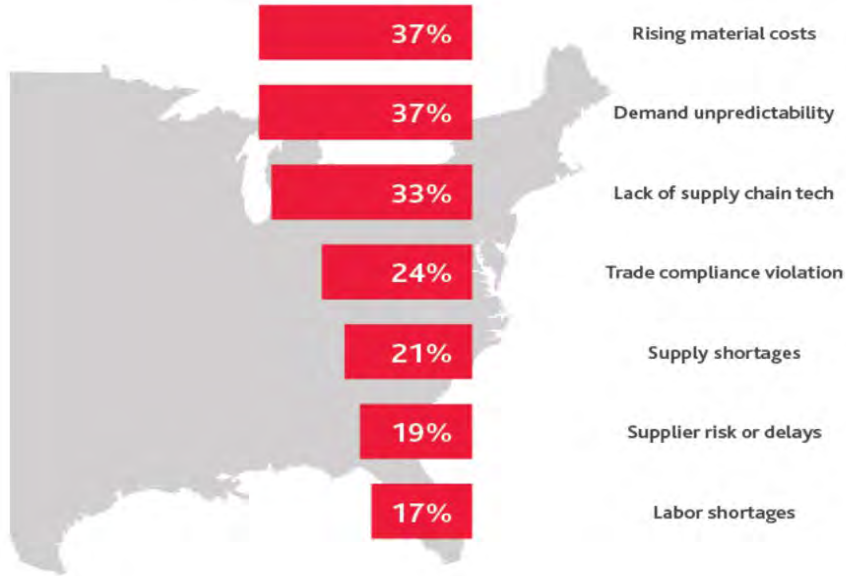
Sources: Bureau of Labor Statistics; Harper Petersen Holding GmbH; Baltic Exchange; IHS Markit; Institute for Supply Management; Haver Analytics; Bloomberg L.P.; authors' calculations.

See: *Global Supply Chain Pressure Index: May 2022 Update*, Gialucxa Benigno, Julian di Giovanni, Jan J.J. Groen, and Adam Noble, May 18, 2022, accessed at <https://libertystreeteconomics.newyorkfed.org/2022/05/global-supply-chain-pressure-index-may-2022-update/> (last visited 11/23/2022).

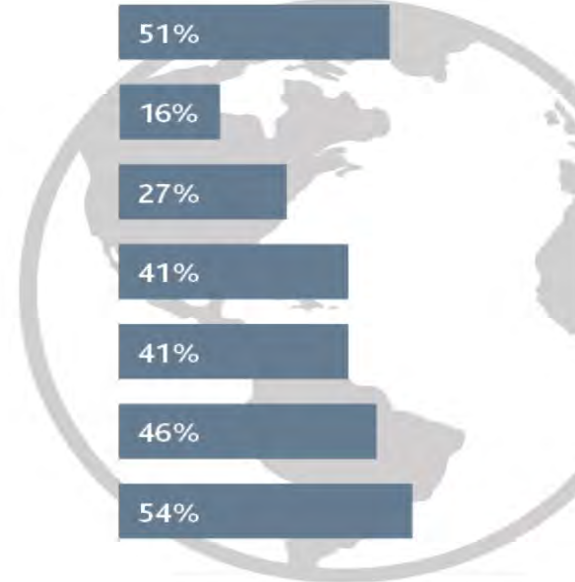
Supply Chain Issues—Life Science Companies

THREATS TO SUPPLY CHAINS IN 2022*

U.S.-ONLY COMPANIES



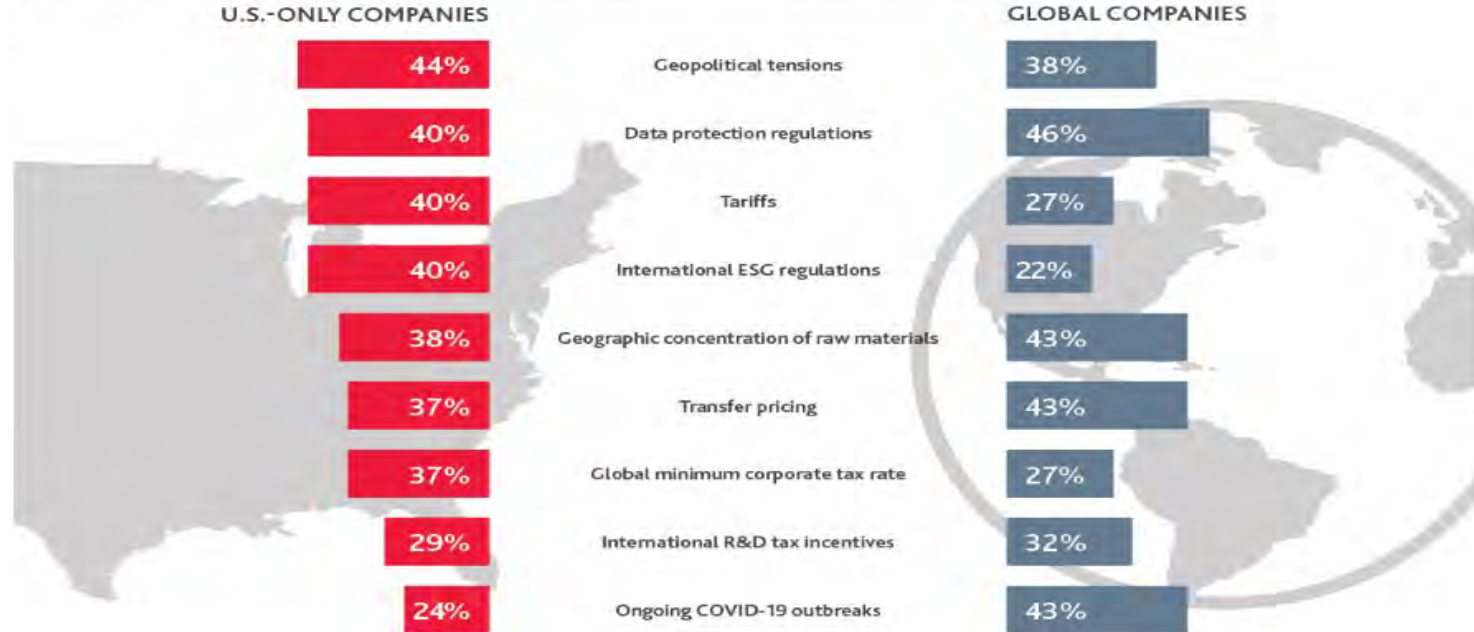
GLOBAL COMPANIES



See: 2022 BDO Life Sciences CFO Outlook Survey, available at <https://insights.bdo.com/cfo-survey-life-sciences-supply-chain> (last accessed 12/5/22).

Supply Chain Issues—Life Science Companies

GLOBAL TRENDS EXPECTED TO IMPACT SUPPLY CHAINS SIGNIFICANTLY IN 2022*



*Note: Responses will not total 100% as this is a multi-select question.

See: 2022 BDO Life Sciences CFO Outlook Survey, available at <https://insights.bdo.com/cfo-survey-life-sciences-supply-chain> (last accessed 12/5/22).

How Supply Chain Issues Can Create Potential Claims

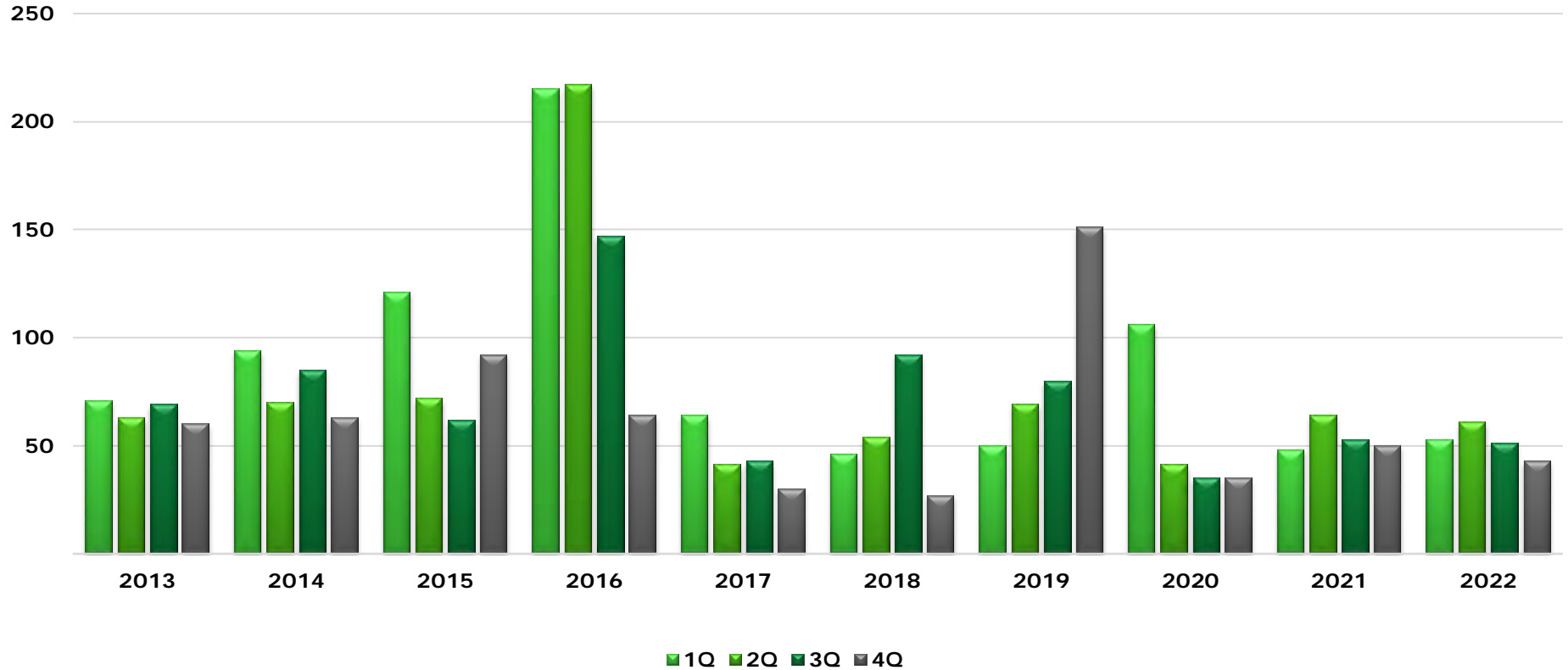
▶ Inability to maintain or fix products

- ▶ EXAMPLE: Your company services medical devices. You are unable to procure appropriate parts to service these medical devices. Your failure to service the devices in a timely manner could result in BI or PD.

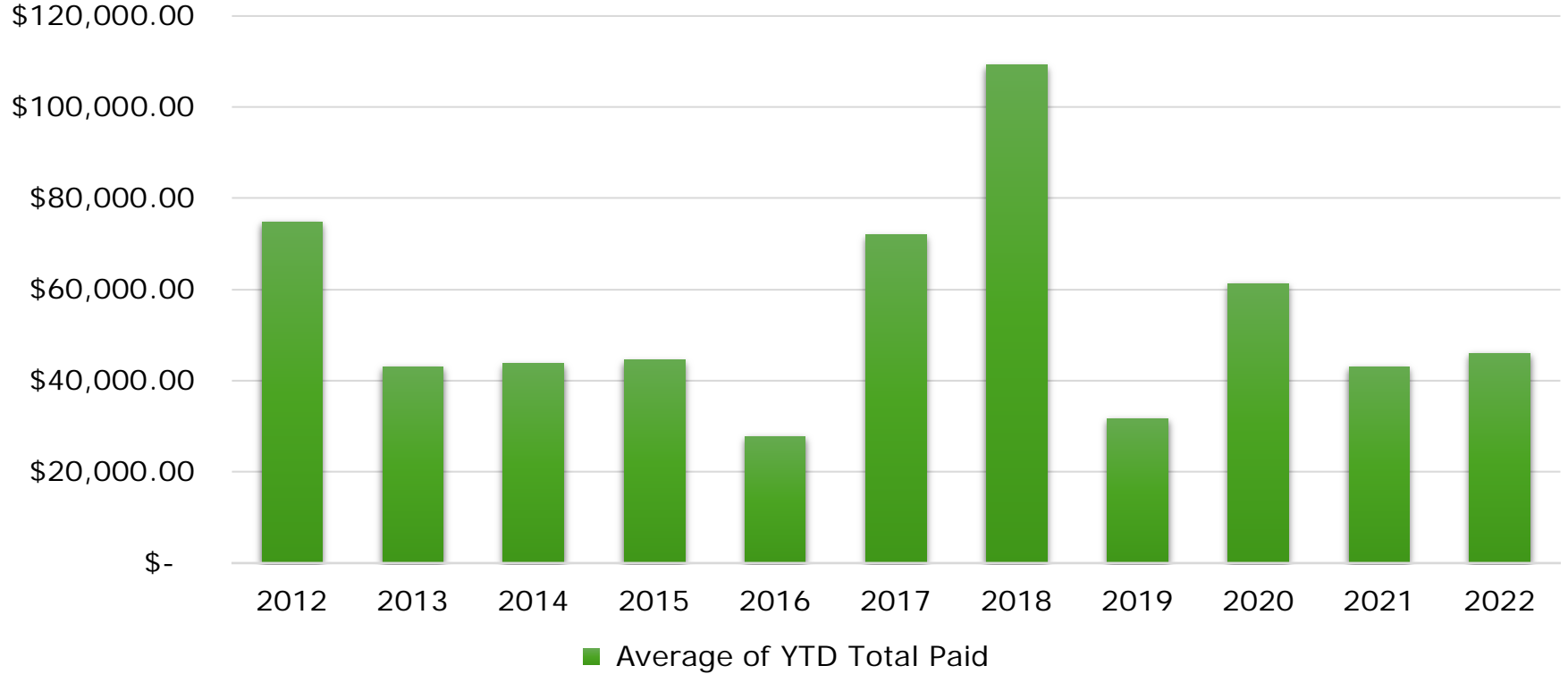
▶ Manufacturer forced to find alternative supply chains or inferior parts to meet its obligations

- ▶ EXAMPLE: Precious metal shortages. Half of the medical devices on the market have semiconductors, which are made of platinum & palladium. Failure to manage the supply chain may result in nonconformities, and ultimately BI or PD.

New Claim Trends (2013 – 2022)



Claim Payment Trends





Emerging Technologies



Augmented Reality

Augmented Reality—What is it?



<https://www.youtube.com/watch?v=xUaBrgsHkPs>

▶ AR is being used widely in the life sciences sector:

▶ Surgery

- Allowing doctors to view CT scans so they can “walk through” a patient’s organ before surgery
- Superimposing key patient data and digital images over surgeon’s field of view so they don’t have to split focus

▶ Medical Training

- AR headsets being used at Case Western to teach med students human anatomy

▶ Pharmaceuticals

- AR being used to show patients how a drug works

▶ Non-life science possibilities:

- ▶ AR litigation to date, in the video game world, has focused on injuries related to:
 - Light sensitivity/epilepsy
 - › Claims largely unsuccessful because no evidence AR causes epilepsy
 - Motion control injuries

▶ Life science possibilities:

- ▶ Incorrect projection of scans used in surgical AR
 - EXAMPLE: AR doesn't properly convert the scan being used resulting in improper placement of surgical screw.
- ▶ Incomplete, inconsistent, or off label information
 - EXAMPLE: Claimant argues that AR being used to explain how drug works contains information inconsistent with what FDA approved.
- ▶ Incorrect or missing information on data projected to doctor during procedure
 - EXAMPLE: Problem with AR doesn't project time sensitive information to surgeon during surgery resulting in BL.



Artificial Intelligence

Artificial Intelligence—What is it



➤ Diagnosis and Disease Identification

- ▶ Cancer diagnosis and disease identification
- ▶ Other areas where AI being used: central nervous system disorders, macular degeneration, depression

➤ Personalized Medicine

- ▶ Taking personal data to predict best potential treatment for that individual's cancer

➤ Pharmaceuticals

- ▶ Improve manufacturing processes; making better predictions about the likelihood of success of a potential drug treatment

➤ Clinical trials

- ▶ Making better predictions on how to design clinical trials, target participants, etc.

➤ Radiology

- ▶ Making comparisons of healthy v. cancer tissues
- ▶ Super fast processing of images

➤ Electronic Health Records

- ▶ Creating electronic health records that are accurate and collect all sources of health information

See: Daniel Faggela, *AI in the Life Sciences: Six Applications*, April 27, 2018, accessible at <https://www.genengnews.com/magazine/314/ai-in-the-life-sciences-six-applications/> (last visited 12/6/2022).

Artificial Intelligence—Claims/Litigation Potential

▶ The AI gets the wrong answer

- ▶ Why did the AI get it wrong?
- ▶ Is this a products liability claim?
- ▶ Insurance coverage?

▶ Privacy considerations (BIPA Lawsuits)

- ▶ Neutrogena is facing a biometric privacy act lawsuit claiming privacy breaches for app that provides personalized recommendations for skin care products.
- ▶ Biometric data allegedly taken without informed consent and was being used to improve algorithm.



Key Developments of 2022

Key Developments of 2022

- a. 2022 Top Cases
- b. MDL Update



Top Cases of 2022

1. *In re Zantac*
2. *City of Huntington v. Amerisource Bergen Corp.*
3. *James v. Medtronic*



In re Zantac Products Liability Litigation

- MDL created February 6, 2020
 - ▶ Judge Robin Rosenberg (S.D. Fla.)
 - ▶ Claims that NDMA formed in the deterioration or metabolism of Zantac caused cancer
- Both sides moved to exclude general causation experts
- Dec. 6, 2022: Judge Rosenberg excluded all 10 of Plaintiffs' general causation experts & granted summary judgment
- Question before the Court was: Is there admissible scientific evidence that Zantac can cause the designated cancers?

City of Huntington v. AmerisourceBergen Drug Corp.



- Rejected numerous opinions by Ps' experts
- 184-page ruling nearly one year after closing arguments in bench trial
- “Nothing unreasonable” about distributors’ sale of opioids to “fulfill legally written prescriptions.”
- Distributors “substantially complied” with obligations to track and report suspicious drug orders
- City of Huntington & Cabell County Commission appealed August 2, 2022 – briefing order issued 11/14/2022

- ▶ Product liability case arising from use of “trial spinal cord stimulator” (Class III device)
- ▶ Medtronic filed MSJ based on federal preemption
- ▶ Court granted SJ on failure to warn claims
 - ▶ Failure to warn of increased risks associated with taking blood thinners preempted
 - ▶ Medtronic did not fail to report adverse events
- ▶ Negligence claim survives SJ
 - ▶ Medtronic rep. adjusted settings in public parking lot

- a. Zantac MDL
- b. Valsartan MDL
- c. Tylenol MDL



- ▶ In light of recent Daubert decision, plaintiffs have a tough road ahead
- ▶ Future litigation likely to be focused outside the MDL, in various state courts: Illinois, California, Pennsylvania, Delaware, New York, and a few others
- ▶ Daubert decision likely to be appealed

- MDL claiming NDMA in Valsartan caused cancer
- Created February 14, 2019
 - ▶ Judge Robert B. Kugler (D.N.J.)
- Background
 - ▶ July 2018, FDA recalled prescription blood pressure and heart drugs
 - Linked to ingredient distributed by Zhejiang Huahai Pharmaceuticals
- As of November 2022, 1,170 total cases added to MDL
- August 31, 2022, CMO set Daubert and dispositive motion deadlines in February 2023
- First bellwether trial unlikely until at least spring/summer 2023

Acetaminophen MDL – A Snap Shot

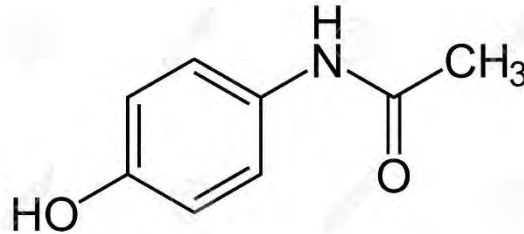
- ▶ MDL re ASD/ADHD claims created October 5, 2022
 - ▶ Judge Denise Cote (S.D.N.Y.)
 - ▶ Nine retailers (CVS, Costco, Family Dollar, Rite Aid, Safeway, Sam's Warehouse, Target, Walgreens, and Walmart)
 - ▶ Retailers argued consolidation premature since manufacturers not sued
 - ▶ Court found plaintiffs commonly allege neurodevelopmental disorders are caused by acetaminophen's in utero impact on brain development, warranting consolidation



Acetaminophen Litigation: General Background

- ▶ Acetaminophen (aka paracetamol or *N*-acetyl-*p*aminophenol) common brand name Tylenol, is one of the most widely-used analgesics

Paracetamol (Acetaminophen)



Acetaminophen Litigation: General Background

October 2019: a study published in the medical journal JAMA Psychiatry found that children with the highest levels of acetaminophen metabolites in their blood at birth had the highest risk of the developmental disorders

2020: researchers from Columbia University published warnings that doctors should re-evaluate the role of the pain medication for pregnant women, after finding that prenatal exposure may lead to impaired neurodevelopment in the fetus

June 2021: the *European Journal of Epidemiology* published research indicating that children exposed to Tylenol during pregnancy were 19% more likely to have autism spectrum disorders and 21% more likely to have ADHD symptoms compared to non-exposed children

December 2021: consensus statement signed by 91 scientists linked prenatal use of acetaminophen to increased (ranging from 1.5-4 times) risk of autism or ADHD in a child

Creation of MDL 3043, In Re: Acetaminophen – ASD/ADHD Products Liability Litigation



👉 **June of 2022:** Ps began filing lawsuits around the country

- ▶ Retailers failed to warn pregnant users of their store-brand acetaminophen products about the neurological risks to the fetus
- ▶ Acetaminophen use during pregnancy increases the child's risk of autism-spectrum disorders (ASD) and ADHD

👉 **Causes of Action:**

1. Failure to warn
2. Negligence
3. Breach of warranty
4. Negligent misrepresentation, and
5. Violations of state consumer protection laws.

Creation of MDL 3043 – Consolidation

- ▶ October 5, 2022 – JPML consolidated and centralized 18 initial cases in SDNY MDL 3043; Assigned to Judge Denise L. Cote
- ▶ Currently approx. 98 cases
- ▶ MDL plaintiffs initially avoided naming manufacturers



MDL 3043: Factual Hurdles for Ps

- ▶ Because the product is an OTC medication, Ps will likely have difficulty proving product ID and product use.
- ▶ Plaintiffs may resort to
 - ▶ Client affidavits;
 - ▶ Medical records from OB; or
 - ▶ Retailer receipts.
- ▶ However, proving that a plaintiff took acetaminophen purchased from or manufactured by a specific defendant will be difficult.

- No causation
 - ▶ No general causation
 - ▶ No specific causation
- No product ID/product use
- Preemption
- Personal jurisdiction



Excessive Verdicts & Factors

3M MDL – A Snap Shot

▶ MDL created April 3, 2019

- ▶ Judge M. Casey Rodgers (N.D.Fla.)
- ▶ Claims 3M's dual-ended Combat Earplugs were defective, leading to hearing loss and/or tinnitus

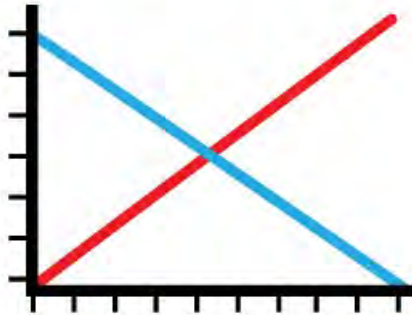
▶ 16 bellwether trials

- ▶ First bellwether (*Estes, Hacker, and Keefer*) March 29, 2021 (165 hours/22 days for trial)
- ▶ Final bellwether (*Beal*) May 9, 2022
 - Presiding Judge Hon. Robin Rosenberg (overseeing Zantac MDL)
 - Nine days of witness testimony and closing arguments

Audience Participation Question #3!

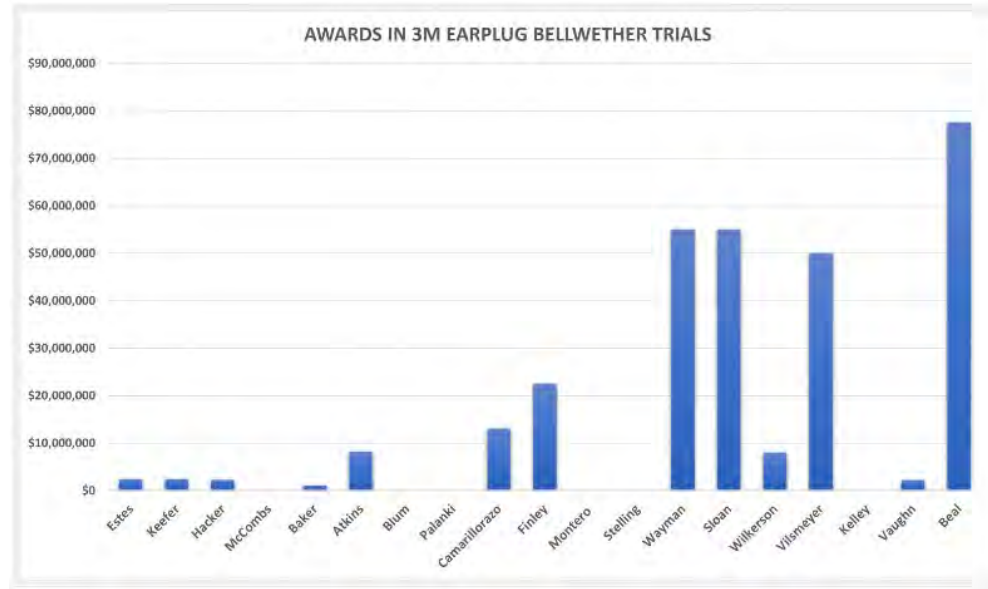
▶ Considering the series of the 16 bellwether trials, has the amount awarded to plaintiffs increased or decreased over time?

- ▶ Increased
- ▶ Decreased



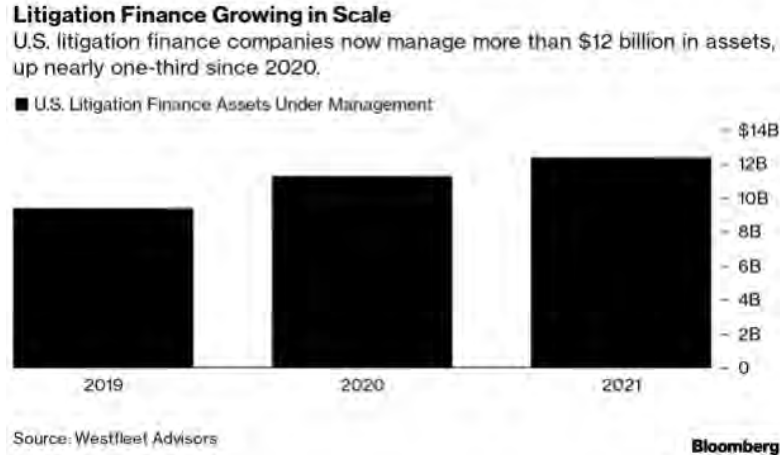
Series of Excessive Verdicts in 3M Earplug Cases

- 16 bellwether trials – 10 plaintiffs' verdicts – approx. \$300 million awarded



Factors in Excessive Verdicts

- ▶ Tort reform rollbacks
- ▶ Class action lawsuits and third-party litigation funding



- ▶ Multi-million and -billion dollar verdicts desensitizing jurors, “normalizing” large awards



Looking Forward to 2023

Looking Forward to 2023

- a. Mallory v. Norfolk Southern Railway Co.*
- b. Federal Rule of Evidence 702*
- c. Valsartan v. Zantac*

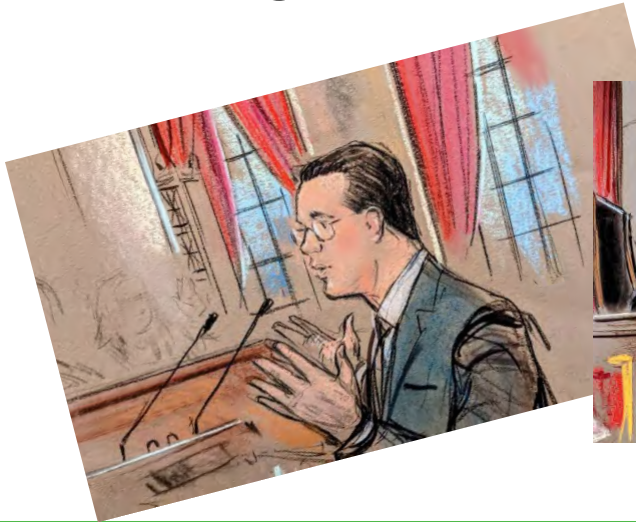


Audience Participation Question #4!

- ▶ Does the Federal Due Process clause prohibit a State from requiring a corporation to consent to personal jurisdiction to do business in the state?
- ▶ Yes
- ▶ No

Mallory v. Norfolk Southern Railway Co.

- ▶ Issue: whether due process clause prohibits state from requiring corporation to consent to personal jurisdiction to do business in state.
- ▶ Oral Argument November 8, 2022



Federal Rule of Evidence 702

Say Goodbye to “*Daubert* Motion”, Hello to New Rule 702



Rule 702: Amendments Effective December 1, 2023

- ▶ The proponent of the expert must demonstrate by a preponderance of the evidence that the expert's knowledge will help the trier of fact, is based on sufficient facts/data, etc.
- ▶ The expert ~~has reliably applied~~ expert's opinion reflects a reliable application of the principles and methods to the facts of the case.

Rule 702: Intent of the Amendments

- ▶ Clarify the admissibility standard within the rule's language; and
- ▶ Emphasize the judicial gatekeeping authority established in *Daubert v. Merrell Dow Pharmaceuticals Inc.*
- ▶ Misapplication of Rule 702:
 - 2/3 of cases – no mention of preponderance of the evidence
 - 13% of the cases – judge described Rule 702 as favoring admissibility
 - Courts incorrectly focused on whether the methodology itself was reliable



FDA Regulatory Update

November 18, 2022: Automated External Defibrillators



- ▶ Premarket approval of new and existing AEDs and AED accessories
 - ▶ AEDs
 - April 2019: FDA sent letters to AED manufacturers which failed to submit PMA, reminding them they cannot market AEDs
 - ▶ AED accessories:
 - February 3, 2022: Manufacturers must file PMA for previously cleared necessary AED accessories (batteries, pad electrodes, adapters, etc.)
 - November 2022: FDA sent letters to AED accessory manufacturers which failed to submit PMA, reminding them they cannot market AED accessories
- ▶ FDA encouraged transition to FDA-approved AEDs and accessories
- ▶ Lists all AEDs with premarket approval
- ▶ Lists all necessary AED accessories with premarket approval



Thank You! Questions?

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